



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,624	01/16/2004	Eric Olson	UTSD:729USD2	1831
7590 02/01/2006			EXAMINER	
Steven L. Highlander, Esq. FULBRIGHT & JAWORSKI L.L.P. Suite 2400 600 Congress Avenue Austin, TX 78701			BERTOGLIO, VALARIE E	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 02/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,624

Applicant(s)

OLSON ET AL.

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-105 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> . |

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **Figures 1A-1E, 2A-2D, and 13 do not contain SEQ ID NUMBERS.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1,2,7, drawn to a polypeptide comprising SEQ ID NO:2, classified in class 530, subclass 350.
- II. Claims 3,4,8, drawn to a polypeptide comprising SEQ ID NO:6, classified in class 530, subclass 350.
- III. Claims 5,6,9, drawn to a polypeptide comprising SEQ ID NO:10, classified in class 530, subclass 350.
- IV. Claims 10-12 and 19, drawn to a nucleic acid encoding SEQ ID NO:2, classified in class 536, subclass 23.1.

Art Unit: 1632

- V. Claims 13-15 and 20, drawn to a nucleic acid encoding SEQ ID NO:6, classified in class 536, subclass 23.1.
- VI. Claims 16-18 and 21, drawn to a nucleic acid encoding SEQ ID NO:10, classified in class 536, subclass 23.1.
- VII. Claims 22-24, drawn to a knockout non-human animal comprising a defective calsarcin gene, classified in class 800, subclass 8.
- VIII. Claims 25-29, drawn to a transgenic non-human animal comprising an expression cassette comprising a nucleic acid encoding a calsarcin polypeptide, classified in class 800, subclass 8.
- IX. Claims 30 and 31, drawn to an antibody that binds a polypeptide comprising SEQ ID NO:2, classified in class 530, subclass 387.1.
- X. Claims 32 and 33, drawn to drawn to an antibody that binds a polypeptide comprising SEQ ID NO:6, classified in class 530, subclass 387.1.
- XI. Claims 34 and 35, drawn to drawn to an antibody that binds a polypeptide comprising SEQ ID NO:10, classified in class 530, subclass 387.1.
- XII. Claims 36-37, drawn to a method of modulating calcineurin activity in vivo via administering a polypeptide, classified in class 514, subclass 2.
- XIII. Claims 38-42, drawn to a method of modulating calcineurin activity in vivo via administering a nucleic acid, classified in class 514, subclass 44.
- XIV. Claims 43-44, drawn to a method of screening for peptides that interact with a calsarcin using a cell, classified in class 435, subclass 7.1.

Art Unit: 1632

- XV. Claims 45,46, 51-57, drawn to a method of screening for a modulator of calsarcin binding to α -actinin in vitro in a cell free system, classified in multiple classes and subclasses.
- XVI. Claims 45, 47-49, 51-57, drawn to a method of screening for a modulator of calsarcin binding to α -actinin in vitro in a cell, classified in multiple classes and subclasses.
- XVII. Claim 45 and 47-57 drawn to a method of screening for a modulator of calsarcin binding to α -actinin in vivo, classified in class 424, subclass 9.1.
- XVIII. Claims 58,59, 64-70, drawn to a method of screening for a modulator of calsarcin binding to calcineurin in vitro in a cell free system, classified in multiple classes and subclasses.
- XIX. Claims 58, 60-62, 64-70, drawn to a method of screening for a modulator of calsarcin binding to calcineurin in vitro in a cell, classified in multiple classes and subclasses.
- XX. Claim 58, 60-70, drawn to a method of screening for a modulator of calsarcin binding to calcineurin in vivo, classified in class 424, subclass 9.1.
- XXI. Claims 71,72 and 77-83, drawn to a method of screening for a modulator of calsarcin binding to telethonin in vitro in a cell free system, classified in multiple classes and subclasses.
- XXII. Claims 71,73-75 and 77-83, drawn to a method of screening for a modulator of calsarcin binding to telethonin in vitro in a cell, classified in multiple classes and subclasses.

Art Unit: 1632

XXIII. Claim 71, 73-83, drawn to a method of screening for a modulator of calsarcin binding to telethonin in vivo, classified in class 424, subclass 9.1.

XXIV. Claim 84, drawn to a method of treating cardiac hypertrophy using protein, classified in class 514, subclass 2.

XXV. Claim 84, drawn to a method of treating heart failure using protein, classified in class 514, subclass 2.

XXVI. Claim 84, drawn to a method of treating Type II diabetes using protein, classified in class 514, subclass 2.

XXVII. Claim 85-89, drawn to a method of treating cardiac hypertrophy using a nucleic acid, classified in class 514, subclass 44.

XXVIII. Claim 85-89, drawn to a method of treating heart failure using a nucleic acid, classified in class 514, subclass 44.

XXIX. Claim 85-89, drawn to a method of treating Type II diabetes using a nucleic acid, classified in class 514, subclass 44.

XXX. Claims 90-94, drawn to a method of inhibiting calcineurin activation of gene transcription, classified in class 435, subclass 325.

XXXI. Claims 95 and 96, drawn to a method of screening for peptides that binds calsarcin in a cell free system, classified in class 435, subclass 7.1.

XXXII. Claims 97-103, drawn to a method of screening for a substance for anti-cardiomyopic hypertrophy activity, classified in class 435, subclass 325.

XXXIII. Claims 97-103, drawn to a method of screening for a substance for anti-heart failure activity, classified in class 435, subclass 325.

XXXIV. Claims 97-102 and 104, drawn to a method of screening for a substance for anti-cardiomyopic hypertrophy activity in vivo in a non-transgenic animal, classified in class 424, subclass 9.1.

XXXV. Claims 97-102 and 104, drawn to a method of screening for a substance for anti-heart failure activity in vivo in a non-transgenic animal, classified in class 424, subclass 9.1.

XXXVI. Claims 97-102, 104 and 105, drawn to a method of screening for a substance for anti-cardiomyopic hypertrophy activity in vivo in a transgenic non-human animal, classified in class 800, subclass 3.

XXXVII. Claims 97-102, 104 and 105, drawn to a method of screening for a substance for anti-heart failure activity in vivo in a transgenic non-human animal, classified in class 800, subclass 3.

Claim 105, as written, is dependent upon itself. However, for the purpose of restriction, it will be interpreted as depending from claim 104 and therefore, is considered part of Inventions XXXVI and XXXII.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct because they are structurally and functionally distinct. The amino acid sequence is different for each polypeptide. The polypeptide of each group is not required for the other. The burden required to search Groups I-III together would be undue.

Invention I and Inventions IV, V or VI are patentably distinct because the polypeptide can be used to generate antibody while the nucleic acid can be used as a probe. Polypeptides are composed of amino acids and polynucleotides are composed of purines and pyrimidines, and therefore, the polypeptides and polynucleotides are structurally distinct. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, the polynucleotides of Inventions IV-VI do not necessarily encode the isolated polypeptide of Invention I. The information provided by the polynucleotide can be used to make different polypeptides. Finally, the isolated protein can be recovered from a natural source using antibodies or affinity chromatography, not requiring the nucleic acid of Inventions IV-VI. Searching Invention I together with any of Inventions IV-VI would be a search burden because the searches are not coextensive. The Inventions have a separate status in the art as shown by their different classifications.

Invention I and Inventions VII or VIII are patentably distinct because the polypeptide can be used to generate antibody while the transgenic animals can be used to screen for modulators of calsarcin binding. The polypeptide is not necessary for the transgenic and the transgenic is not necessary for the polypeptide. The burden required to search Invention I and Inventions VII or VIII together would be undue.

Invention I and Inventions IX, X, or XI are patentably distinct because the polypeptide can be used to modulate calcineurin activity while the antibody can be used to detect the presence of a calsarcin. The burden required to search Groups I and Groups IX, X, or XI together would be undue.

Inventions I and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to generate antibodies.

Inventions I and XIII are patentably distinct because the polypeptide can be used to generate antibody while methods can be used to modulate calcineurin activity using a nucleic acid in vivo. The polypeptide is not necessary for the methods and the methods are not necessary for the polypeptide. The burden required to search Inventions I and XIII together would be undue.

Invention I and Inventions XIV-XXXVI or XXXVII are patentably distinct because the polypeptide can be used to generate antibody while the methods of Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system the methods of Invention XXXII-XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure activity. The burden required to search Invention I and Inventions XIV-XXXVI or XXXVII together would be undue.

Invention II and Inventions IV, V or VI are patentably distinct because the polypeptide can be used to generate antibody while the nucleic acid can be used as a probe. Polypeptides are

Art Unit: 1632

composed of amino acids and polynucleotides are composed of purines and pyrimidines, and therefore, the polypeptides and polynucleotides are structurally distinct. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, the polynucleotides of Inventions IV-VI do not necessarily encode the isolated polypeptide of Invention II. The information provided by the polynucleotide can be used to make different polypeptides. Finally, the isolated protein can be recovered from a natural source using antibodies or affinity chromatography, not requiring the nucleic acid of Inventions IV-VI. Searching Invention II together with any of Inventions IV-VI would be a search burden because the searches are not coextensive. The Inventions have a separate status in the art as shown by their different classifications.

Invention II and Inventions VII or VIII are patentably distinct because the polypeptide can be used to generate antibody while the transgenic animals can be used to screen for modulators of calsarcin binding. The polypeptide is not necessary for the transgenic and the transgenic is not necessary for the polypeptide. The burden required to search Invention II and Invention VII or VIII together would be undue.

Invention II and Inventions IX, X, or XI are patentably distinct because the polypeptide can be used to modulate calcineurin activity while the antibody can be used to detect the presence of a calsarcin. The burden required to search Invention II and Inventions IX, X, or XI together would be undue.

Inventions II and XII are related as product and process of use. In the instant case the polypeptide can be used in a materially different process of generating antibodies.

Inventions II and XIII are patentably distinct because the polypeptide can be used to generate antibody while methods can be used to modulate calcineurin activity using a nucleic acid in vivo. The polypeptide is not necessary for the methods and the methods are not necessary for the polypeptide. The burden required to search Inventions II and XIII together would be undue.

Invention II and Inventions XIV-XXXVI or XXXVII are patentably distinct because the polypeptide can be used to generate antibody while methods of Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system the methods of Invention XXXII-XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure activity. The burden required to search Invention II and Inventions XIV-XXXVI or XXXVII together would be undue.

Invention III and Inventions IV, V or VI are patentably distinct because the polypeptide can be used to generate antibody while the nucleic acid can be used as a probe. Polypeptides are composed of amino acids and polynucleotides are composed of purines and pyrimidines, and therefore, the polypeptides and polynucleotides are structurally distinct. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, the polynucleotides of Inventions IV-VI do not

Art Unit: 1632

necessarily encode the isolated polypeptide of Invention III. The information provided by the polynucleotide can be used to make different polypeptides. Finally, the isolated protein can be recovered from a natural source using antibodies or affinity chromatography, not requiring the nucleic acid of Inventions IV-VI. Searching Invention III together with any of Inventions IV-VI would be a search burden because the searches are not coextensive. The Inventions have a separate status in the art as shown by their different classifications.

Invention III and Inventions VII or VIII are patentably distinct because the polypeptide can be used to generate antibody while the transgenic animals can be used to screen for modulators of calsarcin binding. The polypeptide is not necessary for the transgenic and the transgenic is not necessary for the polypeptide. The burden required to search Invention III and Invention VII or VIII together would be undue.

Invention III and Inventions IX, X, or XI are patentably distinct because the polypeptide can be used to modulate calcineurin activity while the antibody can be used to detect the presence of a calsarcin. The burden required to search Invention III and Inventions IX, X, or XI together would be undue.

Inventions III and XII are related as product and process of use. In the instant case the polypeptide can be used in a materially different process of generating antibodies.

Inventions III and XIII are patentably distinct because the polypeptide can be used to generate antibody while methods can be used to modulate calcineurin activity using a nucleic acid in vivo. The polypeptide is not necessary for the methods and the methods are not necessary for the polypeptide. The burden required to search Inventions II and XIII together would be undue.

Invention III and Inventions XIV-XXXVI or XXXVII are patentably distinct because the polypeptide can be used to generate antibody while the methods of Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system, the methods of Invention XXXII-XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure activity. The burden required to search Invention III and Inventions XIV-XXXVI or XXXVII together would be undue.

Inventions IV-VI are patentably distinct because they are structurally and functionally distinct. The nucleic acid sequence of each Invention is different. The nucleic acid of each invention is not required for the other. The burden required to search Inventions IV-VI together would be undue.

Invention IV and Inventions VII or VIII are patentably distinct because the nucleic acid can be used to generate protein while the transgenic animals can be used to screen for modulators of calsarcin binding. The nucleic acid is not necessary for the transgenic and the transgenic is not necessary for the nucleic acid. The burden required to search Invention IV and Invention VII or VIII together would be undue.

Invention IV and Inventions IX, X, or XI are patentably distinct because the nucleic acid can be used to generate protein while the antibody can be used to detect the presence of a

Art Unit: 1632

calsarcin. The burden required to search Invention IV and Inventions IX, X, or XI together would be undue.

Invention IV and Inventions XII-XXXVI or XXXVII are patentably distinct because the nucleic acid can be used to generate protein while the methods of Invention XII or XIII can be used to modulate calcineurin activity, the methods of Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system, the methods of Invention XXXII-XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure activity. The burden required to search Invention IV and Inventions XII-XXXVI or XXXVII together would be undue.

Invention V and Inventions VII or VIII are patentably distinct because the nucleic acid can be used to generate protein while the transgenic animals can be used to screen for modulators of calsarcin binding. The nucleic acid is not necessary for the transgenic and the transgenic is not necessary for the nucleic acid. The burden required to search Invention V and Invention VII or VIII together would be undue.

Invention V and Inventions IX, X, or XI are patentably distinct because the nucleic acid can be used to generate protein while the antibody can be used to detect the presence of a calsarcin. The burden required to search Invention V and Inventions IX, X, or XI together would be undue.

Invention V and Inventions XII-XXXVI or XXXVII are patentably distinct because the nucleic acid can be used to generate protein while the methods of Invention XII or XIII can be used to modulate calcineurin activity, the methods of Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system, the methods of Invention XXXII-XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure activity. The burden required to search Invention V and Inventions XII-XXXVI or XXXVII together would be undue.

Invention VI and Inventions VII or VIII are patentably distinct because the nucleic acid can be used to generate protein while the transgenic animals can be used to screen for modulators of calsarcin binding. The nucleic acid is not necessary for the transgenic and the transgenic is not necessary for the nucleic acid. The burden required to search Invention VI and Invention VII or VIII together would be undue.

Invention VI and Inventions IX, X, or XI are patentably distinct because the nucleic acid can be used to generate protein while the antibody can be used to detect the presence of a calsarcin. The burden required to search Invention VI and Inventions IX, X, or XI together would be undue.

Invention VI and Inventions XII-XXXVI or XXXVII are patentably distinct because the polypeptide can be used to generate antibody while the methods of Invention XII can be used to

Art Unit: 1632

modulate calcineurin activity, the methods of Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system, the methods of Invention XXXII-XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure activity. The burden required to search Invention VI and Inventions XII-XXXVI or XXXVII together would be undue.

Inventions VII and VIII are patentably distinct because the knockout animal can be used to screen substances for anti-cardiomyopic hypertrophy activity in vivo while the transgenic can be used to modulate calcineurin activity in vivo . The knockout comprising a defective calsarcin and the transgenic comprising a nucleic acid encoding a calsarcin are genetically and structurally distinct. The burden required to search Inventions VII and VIII together would be undue.

Invention VII and Inventions IX, X, or XI are patentably distinct because the knockout animal can be used to screen substances for anti-cardiomyopic hypertrophy activity while the antibody can be used to detect the presence of a calsarcin. The knockout is not necessary for the antibody and the antibody is not necessary for the knockout. The burden required to search Invention VII and Inventions IX, X, or XI together would be undue.

Invention VII and Inventions XII-XXXVI or XXXIII are patentably distinct because the knockout animal can be used to screen substances for anti-cardiomyopic hypertrophy activity while the methods of Invention XII can be used to modulate calcineurin activity, the methods of

Art Unit: 1632

Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system, the methods of Invention XXXII- XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure activity. The burden required to search Invention VI and Inventions XII-XXXVI or XXXVII together would be undue.

Invention VIII and Inventions IX, X, or XI are patentably distinct because the transgenic animal can be used to overexpress a calsarcin in vivo while the antibody can be used to detect the presence of a calsarcin. The transgenic is not necessary for the antibody and the antibody is not necessary for transgenic. The burden required to search Invention VIII and Inventions IX, X, or XI together would be undue.

Invention VIII and Inventions XII-XXXVI or XXXVII are patentably distinct because the transgenic animal can be used to overexpress a calsarcin in vivo while methods of Invention XII can be used to modulate calcineurin activity, the methods of Invention XIV can be used to screen for peptides that interact with a calsarcin, the methods of Inventions XV-XXIII can be used to screen for a modulator of calsarcin binding, the methods of Invention XXIV-XXIX can be used to treat disease, the methods of Invention XXX can be used to inhibit calcineurin activation of gene transcription, the methods of Invention XXXI can be used to screen for peptides that bind calsarcin using a cell free system, the methods of Invention XXXII-XXXVII can be used to screen substances for anti-cardiomyopic hypertrophy activity or anti-heart failure

Art Unit: 1632

activity. The burden required to search Invention VI and Inventions XII-XXXVI or XXXVII together would be undue.

Inventions IX-XI are patentably distinct because they are structurally and functionally distinct. The antibody of each Invention is generated to be specific for distinct proteins. The antibody of each invention is not necessary for the other. The burden required to search Inventions IX-XI together would be undue.

The methods of each of Inventions XII-XXXVII are materially different and plurally independent from each other because each is practiced with materially different method steps and each is practiced independent of the other with different technical considerations. The purpose of Invention XII is to modulate calcineurin activity by administering a polypeptide. The purpose of Invention XIII is to modulate calcineurin in vivo using a nucleic acid. The purpose of Invention XIV is to screen for peptides that interact with a calsarcin using a cell. The purpose of Inventions XV-XVII is to screen for a modulator of calsarcin binding to alpha-actinin using a cell free system (Invention XV) a cell (Invention XVI) or in vivo (Invention XVII). The purpose of Inventions XVIII-XX is to screen for a modulator of calsarcin binding to calcineurin using a cell free system (Invention XVIII), a cell (Invention XIX) or in vivo (Invention XX). The purpose of Inventions XXI-XXIII is to screen for a modulator of calsarcin binding to telethonin using a cell free extract (Invention XXI) or a cell (Invention XXII) or in vivo (Invention XXIII). The purpose of Invention XXIV is to treat cardiac hypertrophy using a protein. The purpose of Invention XXV is to treat heart failure using protein. The purpose of Invention XXVI is to treat Type II diabetes using protein. The purpose of Invention XXVII is to treat cardiac hypertrophy using a nucleic acid. The purpose of Invention XXVIII is to treat heart failure using a nucleic

Art Unit: 1632

acid. The purpose of Invention XXVIX is to treat Type II diabetes using a nucleic acid. The purpose of Invention XXX is to inhibit calcineurin activation of gene transcription. The purpose of Invention XXXI is to screen for peptides that bind calsarcin using a cell free system. The purpose of Invention XXXII, XXXIV and XXVI is to screen substances for anti-cardiomyopic hypertrophy activity in vitro (XXXII), in vivo (XXXIV) or in a transgenic animal (XXXVI). The purpose of Invention XXXIII, XXXV and XXXVII is to screen substances for anti-heart failure activity in vitro (XXXIII), in vivo (XXXV) or in a transgenic animal (XXXVII). The burden required to search Inventions XII-XXXIII together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Valarie Bertoglio', with a long horizontal line extending to the right.

Valarie Bertoglio
Examiner
Art Unit 1632